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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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RECYCLED ANIMAL WASTE

Request for Data, Information, and Views

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 77N-0245]

RECYCLED ANIMAL WASTE

Request for Data, Information, and Views

AGENCY: Food and Drug Administration.

ACTION: Request for data, information, and views.

SUMMARY: The Commissioner of Food and Drugs issues this notice in response to the growing interest in the use of animal waste as animal feed, and in accordance with the Food and Drug Administration's authority with respect to the safety of animal feed ingredients. In this notice, the Commissioner discusses the nature and extent of the practice, the economic and environmental implications, the human and animal health concerns, and various waste processing methods. Specifically, he (1) identifies issues requiring resolution with respect to the feeding of animal waste and invites identification of additional issues that should be considered, (2) invites submission of information and data from research that has already been conducted and solicits comments on additional research needs suggested by the agency, and (3) solicits suggestions as to regulatory controls that might be adopted.

DATE: Submissions must be received on or before June 26, 1978.

FOR FURTHER INFORMATION CONTACT:

Veterinary Drugs: Jack Taylor, Bureau of Veterinary Medicine (HFV-100), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5247.

Foods: William Horwitz, Bureau of Foods (HFF-101), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1301.

SUPPLEMENTARY INFORMATION:

I. INTRODUCTION

This notice is issued to elicit the early involvement of interested citizens in the development and revision of regulations governing the recycling of animal waste, waste which is processed and fed to food-producing animals.

There is an increased interest in processing animal waste and feeding the resulting product to food-producing animals. The processed material is a source of protein and other nutrients; it therefore has economic value to the livestock producer. Since nutrients provided in animal waste may be less costly than those from conventional sources, the feeding of animal waste may ultimately provide economic benefits to the consumer. In addition to contributing to the nation's protein supply, recycling of animal waste may reduce water and air pollution which originates in livestock and poultry facilities. On the other hand, since animal waste could contain disease-producing organisms and parasites, residues of drugs and drug metabolites, and toxic elements and other contaminants of natural and industrial origin, the feeding of animal waste could present hazards to animal and human health unless such contaminants (if present at unsafe levels) are eliminated or reduced to acceptable levels.

In a policy statement (now codified at 21 CFR 500.40) published in the FEDERAL REGISTER of September 3, 1967 (32 FR 12714), FDA announced that it did not sanction the feeding of poultry litter to animals. The agency has since informally extended the scope of its statement to include wastes from other species, although it has restricted enforcement of the announced policy in other ways, as discussed below. In response to inquiries and to indications of increased use, the Commissioner has requested a reevaluation of the agency's present posture, to determine what changes, if any, are justified. He has concluded, however, that the data available at the present time are inadequate to provide a full assessment of the risks involved in the feeding of animal waste. Also, insufficient information is available about ways to minimize these risks by processing or by other measures designed to control the occurrence of harmful substances that could appear in the wastes. Further, the Commissioner may not have available to him all of the data (with respect to safety) that would be needed to provide a basis for the adoption of practical regulatory controls on the recycling of animal waste, since the amount of data needed would vary with the nature and stringency of the controls. For example, less safety data might be needed if the feeding of animal waste is restricted as to species (i.e., there might be more concern about feeding waste to dairy cows that are in production compared with feeding waste to meat animals) or by establishment of withdrawal periods (periods of time immediately before slaughter during which the waste product cannot be fed).

For these reasons, the Commissioner has concluded that no change in the agency's policy is appropriate at this time. However, the Commissioner has also concluded that the agency should solicit data and comments from the public with respect to several central issues. Following evaluation of the comments and data, the Commissioner will determine whether any changes in current agency policy are indicated and, if so, what the changes should be. Any proposed changes will be announced in the FEDERAL REGISTER, and the public will again be invited to comment.

The specific purposes of this notice, therefore, are to (1) identify issues requiring resolution with respect to the feeding of animal waste, and invite suggestions as to additional issues that should be considered; (2) invite submission of information and data from research that has already been conducted, and solicit comments on additional research needs suggested by the agency; and (3) solicit suggestions as to regulatory controls that might be adopted.

PAST ACTIONS BY FEDERAL AGENCIES

In 1965, as a result of interest in the expanded use of poultry waste as animal feed, the United States Department of Ariculture (USDA) formed a committee composed of USDA representatives and an advisor from FDA to determine whether sufficient information was available to assure that animal wastes used as animal feed ingredients were safe and nutritious. Deliberations of that committee resulted in the issuance of the following policy statement by USDA in 1965:

> The feeding of poultry litter to livestock constitutes a potential public health hazard, and it is recommended that the practice not be followed until such time as research provides a method of rendering poultry litter as a safe feed ingredient.

During the subsequent 2 years, FDA received field reports that poultry litter was being used for livestock feed. The field reports, coupled with the concerns expressed by USDA, prompted FDA's publication in 1967 of a statement of policy and interpretation concerning the use of poultry litter as animal feed. That statement (codified at 21 CFR 500.40) pointed out the difficulty of determining the nature and levels of residues of antibiotic drugs and their metabolites in the tissues and byproducts of animals fed poultry litter. It also stated that disease organisms may be transferred from poultry to other animals, and eventually to man, through the use of poultry litter as animal feed. The statement concludes:

> Therefore, the Food and Drug Administration has not sanctioned and does not sanction the use of poultry litter as a feed or as a component of feed for animals. Poultry litter subject to the jurisdiction of the Federal Food, Drug, and Cosmetic Act and offered for use as animal feed may be considered as adulterated within the meaning of section 402(a) (1), (2)(C), and/or (3) of the act.

Although the statement refers only to the use of poultry litter as animal feed, FDA has subsequently taken the position informally that the statement applies to all forms of animal excreta. However, the agency has also informally adopted the position that regulatory action will not be taken unless animal waste intended for use as animal feed were found to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and unless a violation of section 301 of the act (21 U.S.C. 331) had occurred. A food is adulterated if, for example, it bears or contains any poisonous or deleterious substance which may render it injurious to health (section 402(a)(1) of the act); or if it is, or bears or contains any food additive which is unsafe within the meaning of section 409 (section 402(a)(2)(C) of the act). Among the acts prohibited by section 301 is the introduction or delivery for introduction into interstate commerce of adulterated food. Since very

little animal waste intended for use in animal feed moves in interstate commerce, the effect of FDA's announced policy has been to leave regulatory action in this area to the states.

In 1972, USDA formed a task force composed of scientists from USDA, FDA, and the Environmental Protection Agency (EPA), charging it with the responsibility of updating USDA's 1965 policy position in view of technological advances which had occurred in the processing of animal waste, and in light of research findings as to the nutritional value of animal waste. The task force found that the feeding of animal wastes has potential for (1) recovery of nutrients, (2) reduction of costs of animal-derived foods, and (3) amelioration of environmental problems. The task force recommended that more research be devoted to the development of processes by which certain animal wastes could be rendered safe and improved in quality for feeding purposes. Finally, the task force recommended that priority attention be given to health-related research to ensure that no animal or human health hazard will be created by such use, and that processing systems be emphasized which provide clear economic and nutritional benefits.

Because of the existence of the statement that appears at 21 CFR 500.40 and because of the growing interest in the subject, the Commissioner, in 1974, directed the scientific personnel of the Bureau of Veterinary Medicine and the Bureau of Foods to review the various questions concerned with the feeding of animal waste and to determine whether recent scientific data and technological advances reported in the scientific literature supported a sanction by FDA of the feeding of recycled animal waste. FDA's review has involved a considerable expenditure of agency resources. It has identified a number of issues and has resulted in the compilation of a substantial volume of information. However, the review has also revealed a number of deficiencies in the information needed to provide the required assurances of safety. Furthermore, additional information may be needed before the agency can adopt a regulatory control program which will allow restricted feeding of animal waste. Therefore, the Commissioner determined that this notice should be published, and that in the meantime the agency's present policy, as described above, should remain in effect.

II. The Use and Regulation of Animal Waste as Feed

A. Historical Development of Animal Waste Feeding

Research in the use of animal waste as feed for animals began in the 1940's. Some of the first recorded research studies utilized poultry litter as a part of the ruminant diet (Ref. 1) and dried cow manure in the diet of chicks (Ref. 68). Since that time feeding studies using animal waste as a part of the diet of livestock have been conducted at most of the agricultural experiment stations in the United States. The USDA and the EPA have both conducted feeding studies and have supported research through grants. Similar studies have been conducted in several foreign countries, and England has recently adopted a regulation which provides for the use of animal waste as a feed ingredient (Ref. 2).

The research to date has demonstrated that animal waste contains nutrients that can be used either by the species that produces the waste, or by other species. Due to high fiber content, however, both ruminant and poultry wastes are best utilized by ruminants (e.g., cattle and sheep). Poultry waste also contains uric acid, which can be readily used by ruminants, but not by nonruminants, as a source of nitrogen for synthesis of protein.

Animal waste is typically low in energy content and as a result its use is limited to small amounts (25 percent or less) in high energy finishing or fattening diets for ruminants. However, grower or conditioner diets for ruminants may contain larger quantities of waste.

Because poultry waste contains from 30 to 35 percent crude protein equivalent (nitrogen×6.25), it may present an attractive alternative to conventional protein supplements, e.g., soybean meal, especially when prices of the traditional protein sources are high. Ruminant wastes are lower in protein, but can be utilized as a source of fiber in the ruminant diet. Research has shown that poultry can utilize their own processed waste as a portion of the diet (Ref. 3). However, the high fiber and low energy content of ruminant wastes make these wastes unlikely candidates for inclusion in poultry diets, since poultry normally are fed high energy diets. To date, swine wastes (aerobically processed) have been fed primarily to swine. Oxidation ditch-mixed liquor (aerobically processed liquid taken from the surface of ditches into which swine wastes have been directed) has been uitilized as a source of both water and nutrients for finishing swine, and finishing swine wastes have been re-fed to breeding swine. However, only a limited number of studies have been conducted utilizing processed swine wastes as feed ingredients for swine or other animal species.

Although data are not available, it is known that the extent of feeding of animal wastes has increased in recent years. It is also common knowledge that the "recycling" of animal wastes has been occurring naturally for many years (e.g., swine following cattle in search of grain kernels that had not been metabolized, chickens in barnyards, etc.).

B. Processing Methods Used

Several processes have been used to treat animal wastes so that they may be better suited for feeding livestock. It is apparent that animal wastes intended for feeding are currently being processed by both man-made and natural processes.

Animal wastes are ordinarily processed before use or storage for a number of reasons. Wastes are produced continuously in livestock and poultry operations and are, therefore, subject to deterioration unless processed before storage. If the wastes are not processed artificially before they are stored, natural processing will occur, e.g., air-drying or anaerobic decomposition. A second reason is that most wastes must be processed to be acceptable to the consuming species (Ref. 4). A third and related reason is that unless they are ensiled, the wastes must be dehydrated before being mixed with dry feed, to avoid the deleterious effects of high moisture on their components of the diet. Finally, most farmers will insist on processing before feeding, simply as a means of disease control. Strict santitation controls are utilized in most commercial livestock and poultry operations; few managers would risk possible introduction of disease into a feeding operation.

The processes that have been used to treat animal waste range from simple techniques such as air-drying (animal waste is roughly 50 to 70 percent water) to sophisticated mechanical systems. Various animal waste treatment procedures, which have been tested or are in use at the present time on farms as practical process methods, are as follows: (1) Dehydration (air and heat), (2) ensiling (alone or with other feedstuffs), (3) composting, (4) physical fractionation, (5) fermentation, (6) heat treatment, and (7) formaldehyde treatment. Other processes, such as radiation pasteurization and thermoradiation, have been proposed. The Commissioner cautions, however, that radiation of animal feed ingredients would be subject to separate regulation by FDA.

Day (Ref. 5) reviewed several processing methods used to produce dried poultry waste, wastelage and oxidation ditch-mixed liquor. Dried poultry waste from caged layers is produced by drying the raw product at varying temperatures for varying time periods. Processing at high temperatures for short periods is preferred for practical reasons, and results in a granulated product with about 10 to 15 percent moisture. Wastelage is produced by mixing fresh cattle manure with hay or other common feed ingredients containing sufficient carbohydrates to support an acid microbial fermentation, and ensiling the mixture. Oxidation ditch-mixed liquor is a nutrient-rich drinking water obtained from aerobically treated liquid wastes. Manure from a confinement building is collected in an oxidation ditch. The aerobic action of the oxidation ditch (an odorless process) converts organic matter to single-cell protein. Feeding tests have shown that the crude protein content of the diet can be reduced by 2.5 percent when the oxidation ditch-mixed liquor is used as the sole source of drinking water (Ref. 6).

Three commercial methods of processing cattle wastes for re-feeding, the Cereco, Corral, and Grazon systems, were described by Day (Ref. 5). The Cereco and Corral systems involve complex, expensive equipment that limits their use to large feeding operations. The Grazon system can be used for both small and large operations. In all three methods, manure is collected frequently and

processed before major losses of nutrients can occur.

In the Cereco system, manure is collected from the feedlot every 4 to 10 days by a self-loading truck that skims fresh manure from the pens. The manure is then ground and unloaded into slurry pits. After 24 hours in the pits, the slurry is pumped into a liquid-solid separator and is then pressed. The resulting solid product is ensiled. The liquid portion from the press is fermented to encourage the production of single-cell protein; it is then dried, pasteurized, blended with other feed ingredients, and pelleted. The pellets are suitable as cattle, poultry, or fish feed.

In the Corral system, fresh urine and manure are collected daily by a scraper which operates underneath slotted floors in confinement buildings. The wastes are agitated in a holding pit, and then pumped into a mechanical unit that separates the large solids from the liquid. The liquid fraction goes to a holding pond for storage until it is applied to crops for fertilizer by flood irrigation or by a sprinkler system. Solids from the press are moved from the separation unit to be composted, ensiled, or treated by a pathocide process before re-feeding.

In the Grazon system, cattle manure is frequently collected; a formaldehyde solution is added and then mixed in a truck or wagon to obtain "formulage." The treatment is designed to improve the acceptability of the manure, to kill the pathogenic organisms, and to control odors. The treated manure is then mixed with other feed ingredients and fed to livestock.

C. STATE REGULATORY INVOLVEMENT

The National Association of State Departments of Agriculture (NASDA) adopted the following resolution in 1976:

Food remains an important concern to consumers. It is imperative that every effort be made to reduce the cost of production. The use of animal waste properly recycled and blended into livestock and poultry rations can extend our present supply of grain for feeding purposes. Scientists have estimated that approximately 1.7 billion tons of animal waste is produced in the nation each year. This method of disposing of animal wastes has a significant environmental advantage.

Resolved, That the National Association of State Departments of Agriculture in convention in Phoenix, Ariz., November 18, 1976, continue its interest in the recycling of animal wastes and work through its Task Force with FDA to coordinate any Federal initiatives in this area.

Be it further resolved, That we recommend to FDA that it continue its posture of scientific investigation and study toward the development of reasonable and acceptable regulations and this include a joint effort with the states, the industry and academia. Policy No. DFD–2–A Sub.

NASDA also adopted the following resolution a year earlier:

Resolved, That the National Association of State Departments of Agriculture, in convention at Charleston, W. Va., October 9, 1975, recommends that its member states adopt appropriate regulations to recognize dehydrated poultry waste and poultry litter as a commercial feed.

The preamble to the resolution stated that the disposal of dehydrated poultry waste and poultry litter has become an economic burden on producers as well as an ever increasing environmental concern, and when adequately processed such waste and litter are potential sources of economical nutrients.

An understanding of state regulation of livestock and poultry feed is useful in considering state involvement in the control of the feeding of recycled animal waste. All States except Nevada have a commercial feed law; Nevada has only a labeling law relating to animal feed. Many years ago, the Association of American Feed Control Officials (AAFCO) developed a model state feed bill and urged all States to adopt it through state legislative action. The Association of American Feed Control Officials also developed model regulations, which the States were urged to adopt through state administrative procedures. The model feed bill and regulations, if adopted, require all feed manufacturers to register their products with the State. The product labels are reviewed and approved or disapproved. The products are sampled in the retail sales channels and analyzed in the state laboratories to determine if label guarantees are met.

In 1970, the Association of American Feed Control Officials revised the model bill and regulations to include feed mill inspection authority; authority over new animal drugs, food additives, and color additives, as defined in the Federal Food, Drug, and Cosmetic Act; and, by reference, good manufacturing practices regulations issued by FDA. All States have adopted either the old or revised model bill and regulations.

When a State enacts the model bill and promulgates the model regulations (either the original or revised models), it also adopts the "Official Feed Terms" and "Feed Ingredient Definitions" as published in the AAFCO "Official Publication." The Association of American Feed Control Officials has a definition, 60.31, for dried poultry waste. The definition is "tentative," a category which allows use of the article if there is no official AAFCO definition. The provision of 60.31 is as follows:

Dried Poultry Waste (D.P.W.) is a product composed of freshly collected feces from commercial laying or broiler flocks not receiving medicaments.

It shall be thermally dehydrated to a moisture content of not more than 15 percent. It shall not contain any substances at harmful levels. It shall be free of extraneous materials such as wire, glass, nails, etc. The product shall be labeled to show the minimum percent protein, minimum percent fat and percent fiber. (Proposed 1973) NRC 5–14–015.

It may be used as an ingredient in sheep, lamb, beef and dairy cattle, broiler and layer chicken feeds. Broiler and laying rations shall be limited to 20 percent and 25 percent D.P.W. respectively.

Since the moisture content is limited to 15 percent, the practical effect of the definition is to require the drying of the wastes by some processing method.

Any State which has adopted either version of the model bill and regulations could, therefore, allow the use of this feed ingredient in intrastate commerce. However, the Association of American Feed Control Officials definition of dried poultry waste is very restrictive, since it provides only for use of freshly collected feces from caged layers not receiving medicaments. Therefore, some States have promulgated specific administrative regulations, under existing statutory authority, providing for much broader uses of dried poultry waste and for use of other types of animal waste as feed ingredients. The States of California, Colorado, Mississippi, Washington, Alabama, and Virginia have promulgated specific regulations for animal wastes within the past several years, although Mississippi has approved only caged layer waste (DWP). In addition, Georgia, Florida, Oregon, and Iowa have started registering DPW as a feed ingredient, under authority of their previously existing feed laws, without adopting new regulations.

The States with specific regulations have recognized two categories of animal wastes: (1) Those that are either collected from animals that have been fed drugs, or that contain drug residues as identified by testing; and (2) products that are free of drug residues in that the wastes are collected from livestock and poultry that have not been fed drugs, or have been tested and found to be free of drugs. A 15-day withdrawal period (before slaughter) has been established for use of the first category in Virginia. Mississippi, Washington, Alabama, and Colorado require a 30-day withdrawal for the first category. California requires no withdrawal period for the first category, but specifies that the waste shall not contain levels of drugs that could result in unlawful tissue residues or be harmful to animals consuming the product. No use restrictions are placed on the products not containing drugs except that California does not provide for the waste to be fed to lactating dairy animals. Virginia, Georgia, Mississippi, Washington, Alabama, and Colorado allow animal waste not containing drugs to be fed to laying hens and dairy cattle that are in production.

It should be recognized that the Association of American Feed Control Officials ordinarily does not publish a definition until and unless use of the article thus defined has been sanctioned in some manner by FDA. The Association of American Feed Control Officials has adhered to this policy so that feed ingredients that comply with its definitions may be legally used interstate. As stated above, however, FDA's current position is that regulatory action will not be taken unless animal waste intended for use as animal feed were found to be adulterated under section 402 of the act and unless a violation of section 301 of the act had occurred. Thus, the AAFCO definition, as extended by several States, may not conflict with current FDA policy, at least when the waste does not enter interstate commerce.

D. LOCAL VS. INTERSTATE CHARACTER OF USE

Wastes collected from caged and floor-raised poultry, and wastes collected from feedlot cattle, apparently are the primary sources of waste products currently used as animal feeds. Based on information currently available to FDA, swine wastes which have been utilized to date have been re-fed to swine, but only on a very limited scale, and for the most part only on an experimental basis.

Wastes from both caged and floor-raised poultry have been utilized in diets for beef brood cows, dairy cows (experimentally), dairy and beef growing stock, and fattening cattle. Caged layers normally require only periodic medication; their waste when dried contains about 30 percent crude protein equivalent, and about 9 percent calcium and 2 percent phosphorus. Such waste, therefore, is considered by many scientists to be a suitable protein and mineral source for the ruminant animal and has potential for movement in interstate trade channels. For example, wastes from caged birds might be shipped to areas engaged in finishing cattle for market if the costs for drying and shipping do not make the waste economically noncompetitive with other protein and mineral supplements. The value of the waste product as feed is estimated to be from $6 per ton unprocessed to $110 per ton when dehydrated (Ref. 7).

In contrast to cage-raised poultry, floor-raised poultry often have a coccidiostat added to their diet, so the litter material can be expected to contain one or more drugs. Waste collected from floor-raised birds has about the same nutrient value for the ruminant as that collected from caged layers. It is usually ensiled, or dry stacked (piled either outdoors or in open sheds and allowed to undergo a natural heating process). It is readily consumed by ruminant animals if processed by either dry stacking or ensiling.

However, waste from floor-raised poultry is a bulky material due to the content of litter materials (usually wood shavings or peanut hulls) and to date has been used only locally because of its bulk. Therefore, it is not expected that wastes from floor-raised birds will be utilized except to a very limited extent in cattle finishing diets because the areas of the country that produce floor-raised poultry characteristically have few slaughter cattle that have been fed in feedlots. Furthermore, since such wastes are low in energy content they are limited to 25 percent or less of a high energy fattening diet being fed to animals before slaughter. Therefore, even if wastes from floor-raised birds were transported to cattle feedlots, the prospect of occurrence of drug residues in the carcasses is lessened because of limited consumption due to dilution by other feedstuffs.

Cattle wastes are bulky materials and have typically been re-fed to cattle in the same vicinity. Thus, cattle wastes are not expected to enter interstate commercial trade channels.

In summary, it is expected that in the foreseeable future only limited amounts of animal wastes will be transported interstate. Such shipment will most likely be limited primarily to wastes from caged layers, which are not normally fed drugs continuously. Furthermore, because of the local nature of animal waste recycling and the likelihood that some of the recycling will be done on an intrafarm basis, it is probable that much of the interfarm, intrastate movement will be accomplished on a direct farmer-to-farmer basis rather than through commercial marketing.

III. ECONOMIC AND ENVIRONMENTAL CONSIDERATIONS

Nearly two billion tons of solid waste, including bedding material, are produced each year by farm animals. Much of this total cannot be used economically for recycling through livestock, because of factors such as widespread dispersion of the waste over farm and range land, and distance from both waste processing centers and the livestock which are potential consumers of the recycled animal waste materials. A significant amount of the waste can, however, be utilized as animal feed. This portion has been estimated from livestock and poultry numbers provided by the USDA to be 143 million tons annually on a dry basis (Ref. 8).

The traditional method of disposing of livestock and poultry wastes has entailed application to the land surface near the production site. Current trends in livestock production (e.g., concentration of large numbers of animals in feedlots, dairy operations, and poultry facilities; commodity specialization by producers; and geographic specialization of production) have made it increasingly difficult and expensive to dispose of animal waste by land application, especially in view of the transportation costs involved. While land disposal remains the major practice, alternative methods of disposal are needed for an increasing volume of waste. Recycling of animal waste offers potential economic and environmental benefits to both producers and consumers.

A. ECONOMIC CONSIDERATIONS OF RECYCLING ANIMAL WASTE

1. *Nutritional properties of animal waste.* The nutrients inherent in animal waste have traditionally been used in the production of crops for animal and human consumption. Data produced during the last decade demonstrate clearly that animal waste also possesses nutritive value for food-producing animals (Ref. 9). Table 1 provides a brief analysis of the nutrient composition of typical animal wastes. The paper by Bhattacharya and Taylor (Ref. 9) gives a more complete description of the nutrients present in animal waste, including trace minerals, vitamins and other nutrients essential for animal health and growth.

TABLE 1.—*The nutrient composition of some typical animal wastes* [1] [2]

[In percent]

Item	Type of animal waste			
	Laying hens	Broiler litter	Beef steer	Dairy cow
Crude protein	28.0±3.2	31.3±2.9	20.3±0.7	12.7±0.9
True protein [3]	11.3±1.4	16.7±2.4	----	12.5
Crude fiber	12.7±1.7	16.8±1.9	----	37.5
Crude fat	2.0±0.5	3.3±1.3	----	2.5
Ash	28.0±1.5	15.0±3.2	11.5	16.1
Calcium	8.8±1.1	2.4±0.9	.9	----
Phosphorous	2.5±0.6	1.8±0.4	1.6	----

[1] Values obtained from the following sources: References 9, 14, 15, 42, 61-66, and 68.
[2] Mean ± the standard deviation of values expressed on a dry weight basis.
[3] Reference 67

Animal waste derived from several species has been evaluated as a feed ingredient for animals. The material has been shown to be especially useful in the diets of ruminant animals, which can more effectively utilize the fiber and nonprotein nitrogen contained therein. The products of the Cereco system, discussed above, have been shown to have feeding value; the roughage product has a feeding value comparable to corn silage, and the protein substance has been tested successfully as a protein supplement for cattle (Ref. 10).

A number of studies with dried poultry waste suggest that considerable amounts (20 to 40 percent) can be included in the diets of sheep, steers, and cows as an energy and protein source (Refs. 11 through 14).

Broiler litter, another type of poultry waste, has been shown through research to be valuable as a protein supplement for feedlot cattle (Refs. 15 and 17), sheep (Ref. 16), and gestating-lactating ewes (Ref. 1).

There appear to be limits as to the amount of animal waste that can be incorporated into animal diets without loss of efficiency, however. In feeding trials conducted by Fontenot and coworkers (Refs. 15 and 17), steers consuming a 25-percent broiler litter diet had comparable performance (rate of weight gain, feed efficiency, and carcass quality) to steers consuming the control (no litter) diet. However, feeding a 50-percent broiler litter diet reduced both feed intake and performance of the animals.

Steers fed a diet containing 40 percent processed cattle manure made acceptable gains, according to Anthony and Nix (Ref. 18). Anthony (Ref. 19) presented two approaches: mixing whole feedlot manure with a concentrate, or ensiling feedlot manure and Bermuda grass hay to produce a fer-

mented product called "wastelage." Feeding the former mixture proved unsuccessful, as judged by weight gain and carcass grade. However, the latter mixture resulted in satisfactory performance.

2. *Economic considerations.* A detailed economic analysis of the use of animal waste as an animal feed ingredient has not been made by FDA. Any such analysis would have to take into account not only the costs of and returns from feeding processed waste in comparison with other feed ingredients, but also the feasibility and economics of alternative systems for waste utilization. Costs associated with recycling the waste include those for processing, transportation, and storage.

The costs of animal feed ingredients increased dramatically in the first half of the 1970's. This led to accelerated interest in the recycling of animal waste, because of the cost savings that could be realized by substituting processed animal wastes for more expensive ingredients in animal feeds such as conventional protein supplements or grains. Since the use of animal waste as a component of animal feed has the potential for decreasing the cost of producing food from animals, such practice may contribute to lower consumer prices. In some instances, however, savings may be realized only at those times when shortages of traditional sources of animal feed ingredients occur, and prices for these commodities are high enough to make the feeding of recycled animal waste economically attractive.

The economic analysis of recycling animal waste must also include a comparison with alternative waste management systems (Ref. 20). Most important among such alternatives is application of the waste on land, for use as fertilizer. Such applications are among the least expensive methods for utilizing waste. However, larger operations may lack sufficient land for utilization of all the wastes produced.

To the extent that waste recycling is adopted, the land and resources necessary for other methods of waste utilization wll be descreased. Also, to the extent that recovery of nutrients through recycling of animal waste occurs, the practce could result in a decrease in the acreage devoted to production of crops for animal consumption with an expected concomitant increase in acreage available for production of food and fiber for direct human use.

B. ENVIRONMENTAL CONSIDERATIONS

The concentration of large numbers of animals on relatively few acres presents special problems of water pollution, due to percolation of nutrients into the subsoil or entry of wastes into surface waters. Recycling the nutrients contained in animal waste is one of the alternatives that can help limit the extent to which such problems occur.

Although in the aggegate very large quantities of animal wastes are produced each year, the extent of the environmental impact varies widely from one livestock or poultry operation to another. There appears to be no general agreement as to the proportion of the nation's farms that present a pollution threat because of animal waste. For instance, one authority has stated that less than 20 percent of the manure produced by livestock and poultry farms can be considered a pollution threat, and that probably less than 1 percent is actually polluting surface or ground water (Ref. 21). On the other hand, a USDA spokesman has stated that 22 percent of the swine operations in the leading swine-producing States have problems controlling surface water runoff; 26 percent of the feedlot beef operations in the 18 major feedlot States have surface water pollution potential; and about 40 percent of all dairy farms in the 48 contiguous States will have to install new runoff control facilities (Ref. 23).

Water pollution from livestock production operations can be caused by (1) runoff into streams, lakes or ponds, or (2) leaching of nutrients into drainage tiles or subsurface waters. The results can be contamination of human water supplies and recreation sites, and the aquatic habitat of fish and wildlife. Both runoff and leaching can occur either in the vicinity of the feedlot or in fields where the wastes have been spread.

Animal wastes contain the major fertilizer nutrients—nitrogen, prosphorus, potassium and sulfur—as well as many minor nutrients. From a pollution standpoint, nitrogen causes the greatest concern, since it occurs in large quantities, is highly mobile (if in nitrate form), and can be caried either in runoff or percolating water. Nitrogen initially occurs in livestock waste in the ammonium or inorganic nitrogen form, but may be converted to the mobile nitrate form by microorganisms. Nitrogen that is bound in organic matter will also cause pollution if the organic matter is carried in surface runoff, since the nitrogen will subsequently be changed to nitrate form. Phosphorus from animal wastes will enter surface water when the capacitv of the soil to fix and immobilize phosphorus is saturated (Ref. 22).

While water pollution arising from animal wastes has yet to be identified as a critical national problem, the sheer volume of wastes produced and the increased concentration of livestock feeding operations, along with localized problems which have been reported, have resulted in an acceleration of efforts to control such pollution. The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 et seq.) specifically identify concentrated animal feeding operations as "point sources" for which specific controls are to be developed in the near future. The Best Practicable Control Technology Currently Available required by the Federal Water Pollution Control Act Amendments is widely believed to be land application (Ref. 22). However, the application must be made at such a rate that the nutrients can be utilized by crops or fixed by the soil; otherwise leaching or runoff will occur. The amount of nitrogen that can be utilized will probably be the limiting factor, and a safe disposal program will limit the application to 10 to 20 tons of large animal manure (or 5 to 10 tons of poultry manure) per acre per year (Ref. 24).

Alternatives to crop land disposal, besides processing and feeding to animals, include converting the manure to methane gas and composting it to develop products useful to home gardeners and to industry. If the manure is utilized for energy (gas) production, the remaining digested manure is available for use in animal diets or for land application.

Thus, recycling animal wastes may be helpful in controlling water pollution, especially if the system utilized for recycling the wastes controls feedlot runoff, and if waste that would otherwise be spread on land in excessive amounts is recycled instead. Recycling animal wastes is also consistent with the view that an ecologically oriented society must utilize its wastes as resources rather than treat them as useless materials to be discarded.

Animal waste is also a source of air pollution. Air pollution caused by ammonia, amines, mercaptans, and other gases would be markedly reduced where fresh wastes are collected and processed because such gases are produced primarily after the natural bacterial decomposition process begins

IV. HUMAN HEALTH AND AESTHETICS

A. HEALTH CONSIDERATIONS

1. *Introduction.* Processed animal wastes intended for recycling could contain viable microorganisms that are pathogenic for man; drug and drug metabolite residues; toxic elements and other contaminants of natural and industrial origin; and pesticides and other environmental contaminants. In addition, processed animal wastes could contain end products of metabolism, some of which are known to be toxic; however, the nature and mode of action of most of these compounds have not been extensively investigated.

Conventional animal feed ingredients can and do contain many of the foregoing substances. But certain of these biological and chemical agents are cause for separate concern because they are not likely to occur in traditional animal feed ingredients, or because they occur at lower levels. If ingested by animals as contaminants of animal feed, such substances may result in the transmission of infectious disease to humans or in the development of chronic or acute human toxicity. Moreover, recycling of animal waste may enhance the possibility of bioaccumulation of potentially harmful contaminants.

2. *Discussion of individual classes.*—a. *Microbiological contaminants.* Information is available on the mode and extent of transmission of pathogenic microorganisms from animals to man (Ref. 25). It is difficult to determine whether the transfer is any more pronounced in waste feeding than when grain and other conventional feed ingredients are fed to

animals. Estimation of the increased risk to man, if any, from eating animal products from animal fed wastes is difficult because of limited data on the subject.

There are natural concerns for the types and levels of microorganisms present in animal waste when the waste is to be fed to food-producing animals. However, animals normally support a wide variety of microorganisms in their intestinal tract and these microflora constitute a large proportion of the waste matter. Under conditions in which waste is cycled back through the same animal population, the microorganisms present in the waste would either be those present in the feed or those already established in the group of animals. Thus, fresh waste normally contains those particular microbiological species native to the animals which produced the waste. Moreover, animal waste would, for practical reasons, be treated by heat or otherwise processed before being fed, thereby destroying most if not all microorganisms in the waste.

b. *Residues of drugs and their metabolites.* Some animal wastes do not contain drug residues because the animals have not been administered drugs. However, several studies have demonstrated that animal waste derived from animals that have been medicated, or that have consumed medicated feeds, contain residues of the drugs (Refs. 26 through 31). Although these cited studies provide some information, the nature and amounts of drug residues in waste generally are not known. Also, the effect that processing of waste might have on the residues of durgs or their metabolites is not known.

A study by Webb and Fontenot (Ref. 26) revealed that litter collected from broiler chickens treated with penicillin, oxytetracycline, chlortetracycline, amprolium, or nicarbazin contained significant quantities of residues of these drugs, while litter from birds treated with neomycin or zinc bacitracin did not contain detectable amounts of unchanged drug. Furthermore, the authors reported that the edible tissues of beef cattle fed drug residue-containing chicken waste at 25 and 50 percent of their total diet bore measureable (although not violative) levels of one of these drugs, chlortetracycline, even when a 5-day withdrawal period before slaughter was observed. Also, no attempt was made to determine whether metabolites of any of the drugs were present in litter or tissues.

Additional information is required to assess the fate of residues of drugs and their metabolites when drug-containing wastes are fed to animals, especially when the drugs have not been approved for the species being fed the wastes. If drug-containing wastes are fed to species for which use of the drug is approved, the occurrence of illegal levels of residues is likely to be detected through regulatory monitoring programs. However, if drug-containing wastes are fed to species for which use of the drug is not approved, occurrence of illegal residues might not be detected because regulatory monitoring designed to detect such residues may not be performed.

In general, information on the nature and levels of drug-related residues in excreta is not required as a condition of approval for a new animal drug application, although some information of this type may have been developed by sponsors. Also, because considerable differences in metabolism and drug retention may exist from one animal species to another, such information, when it is available on the species of intended use, would be of limited value if waste from medicated animals were fed to an "unapproved" species. The approved use of certain medicated feeds is made possible by the imposition of a withdrawal period for many drugs that permits depletion of drug residues to levels that are safe for human consumption. The withdrawal period is enforced by the use of analytical procedures specifically designed to monitor tissue residues resulting from a particular drug use. This monitoring program, which is conducted by the USDA is not at present specifically designed to monitor tissue residues from animals fed waste produced by other animals that may have transformed the drug into metabolites with undetermined physical and biological properties.

Although the several studies cited above measured drug residues in waste, these studies focused on parent drug compounds and did not take into account the possibility that the major part of the residues may be drug metabolites. Although in many cases, the drugs will have been largely biotransformed by the first species into metabolites of less toxicological concern, this will not always be so. Furthermore, there is a possibility that bioaccumulation of parent drugs or metabolites, or a combination thereof (see discussion of heavy metals, below), may occur in the waste. This possibility should be considered in formulating diets that include animal waste as an ingredient. Finally, data are available on a relatively few drugs and, therefore, are not available on a wide enough spectrum of drugs in terms of absorption and metabolism characteristics. In summary, the data that are available do not resolve all of the questions of human safety that are raised by the possibility of occurrence of residues of drugs and drug metabolites in recycled waste.

c. *Toxic elements, contaminants of natural origin, and pesticides.*—i. *Toxic elements.* FDA is concerned about the entry of toxic elements into the food chain. This concern is based in part on the possibility of increases in concentration of toxic elements in edible animal tissues so as to affect the safety of the tissues for human consumption. The toxic elements of greatest concern are mercury, cadmium, lead, arsenic, and selenium.

Conventional feed constituents may contain unavoidable traces of toxic elements derived from the environment (Ref. 32). For example, fish meal may contain mercury and arsenic, and plant products may contain cadmium, lead, and selenium. Levels of these elements in animal feed are variable (Ref. 33). For instance, the levels present in crop products will depend on the geographic location and the practices used in growing the crops. Levels of mercury in fish meal will depend on source and species of the fish used. In general, the levels of these elements normally present in animal feeds are not sufficiently high to cause concern for animal health, nor are they likely to result in unacceptable residues in meat or meat products.

However, because certain heavy metals such as lead, inorganic mercury, and cadmium appear to be poorly absorbed by animals, there is a potential for these metals to exist at higher levels in animal waste than in conventional feed ingredients. The reason is that a large proportion of the ingested feed is absorbed, and almost all of the unabsorbed elements initially present in the feed are, therefore, concentrated in a relatively small amount of fecal matter. Thus, recycling of waste, especially over multiple cycles, could result in significant increases in the levels of these elements in feed derived from animal waste, and could contribute to a concomitant increase in the residues of these elements in the tissues and organs of animals fed the recycled waste. In addition, it is possible that increases in the levels of residues of these elements in the tissue may occur because of (a) species differences, i.e., the element of concern may be more readily absorbed in a second species, and (b) the fact that, as a result of metabolism or digestion, or because of heat, chemical or other waste treatment, the element may be converted into a form that is more readily absorbed.

One study has shown that bioconcentration may occur with potentially toxic elements in an animal's waste, compared to the levels in its feed (Ref. 34). On the other hand, a study in poultry has shown that continuous recycling of waste for 33 cycles over a period of 400 days did not result in increased levels of mercury, copper, and zinc in tissues and excreta (Ref. 35).

Potential problems exist with regard to the toxic elements lead, cadmium, and mercury, which are known to accumulate to some extent in muscle tissues and/or edible organs of animals when absorbed. Exposure of food animals to increasing levels of these toxic elements could result in excessive residues in edible tissues. Other elements such as arsenic and selenium are known to be depleted from edible tisues of animals following withdrawal from exposure, and are less likely to cause toxicological problems. It should be noted also that muscle tissues, which constitute virtually all of the edible tissues of food-producing animals, are relatively poor accumulators of the five elements of concern. On the other hand, higher than normal concentrations of these elements in milk and eggs, which represent significant portions of the human diet, are possible.

In summary, it is possible that bioconcentration and biotransformation of toxic elements occur in animals so that higher levels would be found in waste compared to other feed ingredients. Additional information on the levels and

and chemical forms of toxic elements in traditional animal feed components, such as grain and tankage, as well as information concerning the effect of repeated recycling of waste on the levels and chemical forms of such substances, therefore, is needed. These studies should clarify, and assist in the evaluation of, the effects of animal waste re-feeding upon tissue residues of toxic elements.

ii. *Use of "toxic elements" as drugs.* Arsenic compounds are commonly used as medication for broiler chickens, and significant levels of arsenic residues normally occur in the poultry waste. The rapidity of metabolism of arsenic in ruminants has not been fully established, although it is possible that arsenic is rapidly excreted, as is know to be the case in other animal species. Additional studies need to be conducted in this area (Ref. 28).

iii. *Other toxicants of natural origin.* The accumulation of contaminants of natural origin other than toxic elements that may be expected to be found in animal waste may also be of concern. Limited data are available concerning the levels and toxicological significance of such compounds as hormones, products of cellular decomposition, and mycotoxins—all of which may be expected to occur in animal waste. There is no particular reason to believe, however, that the presence of these substances in waste would be any more of a contamination problem than in traditional feedstuffs, which may contain similar amounts of such substances (Refs. 31, 32, and 45).

iv. *Mineral supplements.* Mineral supplements include a large group of elements that are considered essential for animal health (Ref. 36). These elements include so-called "major" elements from a nutritional standpoint (e.g., calcium and phosphorus), and "minor" elements (e.g., manganese and iron). The feeding of waste could result in the addition of variable amounts of these mineral supplements to animal feeds, and could cause undesirable residue levels in edible animal tissues (Refs. 37 and 38). However, any nutritional imbalance caused by the use of animal waste will most likely be corrected by proper feed formulation. For example, feed formulation could be based on periodic sampling, or on the mineral content listed in nutrient composition tables and other published sources.

v. *Pesticides.* Several studies have detected residues of pesticides or their metabolites in animal wastes (Refs. 15, 39, and 43). However, a study by Fontenot et al. (Ref. 15) found no difference in pesticide residues in liver and fat from sheep fed broiler litter, compared with control animals and the levels in both groups were low.

Effects of biodegradation and bioaccumulation in tissues should serve to reduce the amount of indirectly added pesticides in animal waste to a level below that in the original feed ingredients ingested by the animal. Therefore, unless these chemicals are added directly to the waste, problems with pesticide residues in animal waste are not expected to be any greater than they are at present as a result of residues on traditional animal feeds and feed ingredients. However, additional information may be needed to determine whether controls related to the use of disinfectants in livestock and poultry sanitation programs—where the disinfectants are applied to, or in the vicinity of, wastes that are intended for feeding—are needed.

Furthermore, if it becomes a practice to use pesticides directly on waste to control insects, fungi, etc., during its processing, storage, or use as feed, it will be necessary to establish tolerances for pesticide residues on waste. It will also be necessary for sponsors of future pesticide petitions to considere the effects of residues of their product in animal waste.

3. *Summary.* Although experience to date has provided no evidence that use of animal waste as animal feed presents hazards to human health (Refs. 43, p. 1273), the available information is not adequate to lay to rest reasonable concerns about the proposed practice. The possible transmission of pathogenic microorganisms to man, the likelihood that residues of drugs and their metabolites would occur, and the possible appearance of residues of other deleterious substances indicate the need for additional research.

B. AESTHETIC CONSIDERATIONS

The Commissioner relaizes that many individuals might find feeding of animal waste to food-producing animals to be repugnant based on aesthetic rather than safety considerations. It must be recognized, however, that coprography (the eating of excrement) is natural among many wild and domestic animals. In addition, placing swine or poultry in feedlots or on pasture following steers in order to recover nutrients from beef waste is standard animal management practice on some farms. For some time, it has been FDA policy to allow diversion of rodent- or bird-contaminated human food to feed for food-producing animals following heat treatment appropriate to destroy microorganisms that may have an adverse effect on animal or human health (Ref. 40).

Finally, it should be noted that studies have shown that feeding animal waste to food-producing animals did not cause a change in the composition of edible tissues, and that the palatability and acceptability of meat from animals fed processed waste were found not to differ from control animals (Refs. 3, 15, 41, and 42).

V. ANIMAL HEALTH CONSIDERATIONS

A. INTRODUCTION

Considerable research has been devoted to evaluating potential health hazards to animals that might result from feeding animal waste. These potential hazards include disease-producing organisms and parasites, mycotoxins, toxic metals, and other substances; they are discussed in greater detail below. As described elsewhere in this document, feeding tests with food-producing animals have generally shown that those fed waste as part of their diet grew at rates comparable to control animals that had not been fed waste. Some of these experiments have been designed specifically to identify and measure the effects of potentially harmful substances, while in other studies this information has been obtained incidental to performance studies. The fact that numerous experimental animals in different localities have maintained a high level of production while receiving diets that contain waste derived from various sources and processed by varying methods is strong evidence that few animals health problems may be expected from the feeding of animal waste to animals. This is particularly true when the wastes are processed as discussed in this section and in sections II and VI.

B. INDIVIDUAL CLASSES

1. *Disease-producing organisms and parasites.* From the experience to date, no direct disease-related problems have been reported from including poultry manure in practical diets for beef cattle, sheep, and dairy cattle; feeding cattle manure to cattle and chickens; feeding caged layer manure to layers; or feeding swine manure to swine, according to a review of the literature made by Fontenot and Webb (Ref. 43).

With respect to parasites, Johnston et al. (Ref. 44) fed 24 beef calves diets containing three levels of dried feedlot wastes (0, 10, and 15 percent). Significant numbers of parasites were recovered from only a few animals, and the distribution of parasites suggested that there was no association with the consumption of feedlot wastes.

As discussed in section VI, studies have shown that proper processing and handling may substantially reduce or eliminate disease-producing organisms and parasites that occur in animal waste.

2. *Mycotoxins, heavy metals, and other substances.* Mycotoxin contamination of animal excreta should not be expected to be any greater problem than is the problem of mycotoxin contamination of grains, provided that animal wastes are stored and processed under conditions whereby fungal growth and toxin production is prevented. Studies of fungal mycotoxins in feed and poultry litter by Lovett (Ref. 45) showed that the feed contributed all but 2 of the 13 toxigenic fungal cultures isolated from the litter.

There have been a limited number of published reports of adverse effects on animal health and nutritional status when wastes have been fed to farm animals. A marked copper toxicity was observed in sheep (which are more sensitive to high copper levels than other farm animals) that had been feed diets containing either 25 or 50 percent broiler litter for 137 days (Ref. 38). Griel et al. (Ref. 46), reporting on a clinical experience on one farm, observed abortions in beef cows that had been fed a diet containing poultry litter which was thought to contain excessive quantities of estrogens. The chickens had been treated with an estrogenic hormone, dienestrol

diacetate, the use of which has since been discontinued. The exact mechanism causing the reproductive problems was not established; however, the authors suggested that a hormone imbalance was involved.

Smith et al. and Lindahl et al. (Refs. 47 and 48) compared pelleted diets containing either dehydrated diary cattle manure (38.5 to 95 percent of the diet, depending on the treatment group) or alfalfa for breeding and gestating ewes. The high-level manure diets did not satisfy the nutrient requirements of ewes during late pregnacy, and abortion rates were high in these groups. The problem was solved by these researchers by (a) adding straw to the diets to provide bulk, which slowed the rate of passage of the material through the digestive system, thus allowing for more complete rumen fermentation and eventual absorption of nutrients; and (b) correcting the mineral imbalance by changing the amounts of phosphorus and magnesium added to the diets (Refs. 49 and 50).

Available scientific information indicates that such adverse nutritional effects of waste feeding can be controlled by proper diet formulation. It is possible that information adequate to allow livestock producers to avoid such nutrition-related problems could be provided through educational programs such as those conducted by the cooperative extension services in each of the States.

VI. Waste Processing Methods

Unprocessed animal waste may harbor parasites (such as *Ascaris*), bacteria (such as *Mycobacterium*), fungi (such as *Candida*), and viruses (such as influenza) which, singly or in combination, are animal and human pathogens. To minimize the possibility of animal disease and the consequent threat to human health, it appears to be necessary to subject waste used as feed to treatment that would destroy these pathogens, or reduce their occurrence to levels that do not present health concerns. Because most pathogens are fairly sensitive to drying and heating, it seems probable that these attributes could be used as a basis for developing effective processes. For instance, processing at 65° C for 15 to 30 minutes will eliminate most known pathogenic organisms that might be of concern.

Some research information exists which indicates that animal wastes may be made free of many microorganisms by proper handling and processing, i.e., ensiling, composting, heat-treating, and chemical-treating (Refs. 9, 43, and 51).

Several studies have reported on the presence of *Salmonella* and on the effects of various treatments on *Salmonella* content. Strauch and Mueller (Ref. 52) reported that fresh manure from caged layers rapidly undergoes a process of "autosterilization" with respect to *Salmonella*. Kraft et al. (Ref. 53) tested excreta from 91 poultry houses and found 29 percent positive for *Salmonella*. The authors also reported testing fresh and old samples of excreta from caged poultry and found from less than 1 to 34,000 *Salmonella* per gram (on a dry weight basis) in 8 of 12 fresh samples of excreta and from less than 1 to 148 *Salmonella* per gram (on a dry weight basis) in 3 of 6 samples of old excreta. Since higher concentrations were found in caged housing than in floor-raised housing, the authors concluded from the data that cage housing may promote the shedding of *Salmonella*.

In a study of poultry litter, Lovett et al. (Ref. 54) examined samples of woodchip litter from four farms over a 12-week period. The litter from all farms contained species from the Citrobacter group. *Salmonella arizonae* was isolated from three of the four farms. On one of these farms, *Salmonella arizonae* did not appear until after 9 weeks of litter use. When it appeared, the concentration was 10^6 per gram of litter and the appearance coincided with an elevated mortality rate in the poultry which were producing the waste. Both the elevated mortality rate and *Salmonella arizonae* isolates continued for the remainder of the sampling period. The study does not indicate the source of the *Salmonella* infection, but appears to demonstrate that wastes containing high levels of *Salmonella* may be accompanied by overt signs of infection in poultry.

The heat resistance of *Salmonella* in poultry litter has been studied by Messer et al. (Ref. 31). In these studies a treatment of 63° C for 60 minutes killed all *S. typhimurium* and *S. pullorum* in woodchip litter containing 24 percent moisture and in corncob litter with 17 percent moisture.

Other studies regarding *Salmonella* content have involved composting and ensiling. *Salmonella* have been found to multiply under certain conditions of temperature when sludge was composted by windrowing (Ref. 55). On the other hand, a report by Whipple (Ref. 56) indicated that poultry litter became negative for *Salmonella* at the end of a 7-day ensiling period.

McCaskey and Anthony (Ref. 57) compared the survival of *Salmonella* inoculated in an ensiled manure-feed mixture containing 45 parts ground shell corn, 15 parts corn silage, and 40 parts of manure from beef steers confined on concrete with the survival of *Salmonella* inoculated in a manure slurry. Following 3 days of storage at 25° C, 25 of 27 inoculated samples of the manure slurry contained surviving *Salmonella*, but no survivors were found in the 27 inoculated ensiled manure-feed mixtures. In a 4-day study, dramatic reduction of other microbial populations occurred, approximately 17-fold for yeast and mold and 800-fold for coliforms. Further studies by these investigators have shown that acid produced by bacteria in the ensiled manure-feed mixture is highly inhibiting to *Salmonella*. A pH range of 4.0 to 4.5 or lower and a temperature range of 25 to 35° C in the silage were responsible for reduction in organism populations.

Studies by Caswell et al. (Ref. 58) showed that ensiling broiler litter with high-moisture corn grain (26.3 percent moisture) greatly reduced coliforms and total bacterial counts compared to values for the nonfermented product.

Day (Ref. 5) reported on use of the Grazon system which utilizes a formaldehyde solution to kil pathogenic organisms. Data collected indicate that treatment of cattle waste with a 0.74 percent formaldehyde solution destroys microbial activity and prevents mold growth for a minimum of 3 months.

Several studies have been designed to study inactivation of parasites. Ciordia and Anthony (Ref. 59) reported on the inactivation of all larvae of three gastrointestinal nematodes after infected feedlot manure and hay were ensiled in Harvestore silos for 4 weeks.

Mycobacteria such as *M. avium*, *M. intracellulare*, and the anonymous group of mycobacteria are of particular concern because they can cause tuberculosis in animals and in man. Some data are available on the inactivation of mycobacteria by heat (Ref. 60); however, very little is known about the presence or persistence of these microoranisms in unheated animal waste and in animal waste that has been ensiled.

In consideration of all these factors, the Commissioner concludes that some form of processing is probably required for the elimination, or reduction to safe levels, of pathogens in waste before its use as animal feed. As noted above (section II.B.), animal wastes are normally processed before re-feeding. It is not known, however, whether all methods currently being used result in the elimination or reduction to safe levels of all pathogens. As discussed above in this section, there are indications that some methods currently used do result in products that are free of many microorganisms. Nevertheless, specific parameters for suitable processing techniques are not available to FDA at this time. An outline of research needed in this and other areas of human safety is provided in section VIII.C.

VII. Legal Considerations

Since this notice does not incorporate a specific proposal, the following discussion represents a preliminary legal assessment, and is provided for background information and for comment. It is subject to modification and/or elaboration following assessment of the comments received in response to this notice, and the formulation of proposed regulatory action, if any.

A. Jurisdiction

The FDA's jurisdiction over animal feed ingredients derives from several sections of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.): Section 201(f) defines "food" to include "articles used for food or drink for man or other animals." Section 402 states that a food shall be deemed to be adulterated if, among other things, it bears or contains any poisonous or deleterious substance; or if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409 of the act. Section 403 defines misbranded food, and

section 512 provides for regulation of new animal drugs, as well as regulation of animal feeds that contain new animal drugs.

Although an animal feed or animal feed ingredient may be adulterated or misbranded within the meaning of the act, a violation of the act does not occur unless an interstate commerce element is present. For instance, "the introduction or delivery for introduction into interstate commerce of any food * * * that is adulterated or misbranded," and the causing thereof, are among the prohibited acts listed in section 301 of the act.

As discussed above in section II.D., relatively little recycled animal waste per se is likely to enter interstate commerce. However, the Commissioner's position is that the agency may, under the act, effectively regulate animal feed ingredients on the theory that (1) delivery of live animals or their products to a slaughterhouse or other facility may constitute causing the introduction or delivery for introduction into interstate commerce or adulterated food, and (2) such animals, or the products of such animals, have been contaminated by one or more ingredients in the animals' feed. This theory is based on the responsibility of FDA for assuring that animal feeds are safe, not only for the animal but also for the ultimate consumer of meat, milk and eggs that enter interstate commerce. The Commissioner is further convinced that a sale of animal waste materials need not have occurred to sustain a finding that the "commerce" element is present; the recycling of animal waste on the farm to food-producing animals is sufficient for a finding that commerce is involved, since the animals (or their products) will be introduced into commerce when they are marketed.

On the other hand, the exercise of jurisdiction over animal feed ingredients on the basis of the preceding theory is not mandated by the act; in proper cases, the Commissioner may choose not to act, on the basis of considerations such as the feasibility of federal regulation, limits on agency resources, and the likelihood that other agencies will regulate the recycling of animal waste.

Nevertheless, actions may be taken under authority of the Federal Food, Drug, and Cosmetic Act that might obviate any part of the regulatory activities of the States. Federal action based on the finding that interstate commerce has occurred could, therefore preempt state regulation, even though the latter may be intrastate-focused, where the two regulations conflict. See, e.g., *Jones* v. *Rath Packing Co.*, — U.S. —, 97 S. Ct. 1305, rehearing denied — U.S. —, 97 S. Ct. 2201 (1977). Also as a general rule, the fact that some States might have already moved to regulate substances that are within the scope of the act would not preclude FDA from exercising its overriding authority.

Essentially, the agency faces three alternatives for regulation of animal waste intended for use as animal feed: (1) regulate only such waste which is shipped in interstate commerce; (2) regulate such waste which is shipped in interstate commerce as well as that sold commercially in intrastate commerce; or (3) regulate all such waste, whether or not it is sold commercially interstate or intrastate. As a matter of discretion, the agency may not wish to regulate intrastate recycling of animal waste, especially when the waste is not sold commercially. For example, there may be practical reasons, relating to the difficulty of regulation, why effective federal control over the recycling practice at the farm level could not be expected at the present time. It is beyond the current resources of FDA to identify all those farmers who might utilize the recycling practice and to maintain a current updated registry of those farmers, for the purposes of assuring FDA officials that animal products that enter into interstate commerce from such farms have been produced from feed ingredients that did not contain harmful levels of deleterious ingredients. Further, the fact that the predominant species of livestock and the degree of interest in recycling vary greatly from one State to another indicates that intrastate recycling might be more effectively controlled by local regulations tailored to the situation in each State.

The possibility of a joint federal-state regulatory program suggests an alternative for control of the feeding of animal waste. As discussed above, the FDA's authority under the Federal Food, Drug, and Cosmetic Act extends to the regulation of all animal feed ingredients. In practice, however, the agency has chosen to concentrate primarily on regulation of medicated feeds. Moreover, FDA's regulatory program related to animal feeds has typically relied heavily on a cooperative federal-state effort. Standards have been established at the federal level, but in the case of the majority of the States, the inspection is done by state feed officials. The federal-state programs have been devised in large part because of the nature of the animal feed industry, as well as the limitations on the manpower of FDA. Such programs might be considered in the case of recycled animal waste.

B. LEGAL STATUS OF RECYCLED ANIMAL WASTE

The FDA's regulatory position regarding recycled animal waste must be established within a framework which includes determination of the legal status of the recycled material. Several alternatives, each having different implications for those who use the material, are possible. 21 CFR 500.40 is a statement whose purpose is to advise individual States and the users of the agency's current position. Such a statement of policy and interpretation, unaccompanied by other regulations, typically requires the agency to show, on a case-by-case basis, that a violation of the act had occurred. Indeed, as stated elsewhere in this notice (see section I), the agency's present position is that regulatory action will not be taken unless animal waste intended for use as animal feed were found to be adulterated under section 402 of the act.

To minimize the difficulties of proving adulteration in each case, FDA could propose to declare recycled animal waste to be a food additive. Alternatively, the agency could propose to affirm the substance as GRAS (generally recognized as safe), as defined in section 201(s) of the act, if processed in accordance with specified standards.

Declaration that the recycled animal waste material is a food additive could be undertaken under sections 201(s), 409, and 701(a) of the act, and 21 CFR 570.38 of the regulations. If, after giving notice and providing opportunity for comment, the Commissioner finds that there is a lack of convincing evidence that the material is GRAS, it would be declared to be a food additive as provided in 21 CFR 570.38(b)(3). Conditions for use (including tolerances) could then be prescribed under a food additive regulation, or the Commissioner could declare that use of the substance is prohibited. However, the variability in composition of recycled animal waste could be an obstacle to approving the use of all waste under a single food additive regulation. For example, section 409(b)(2)(A) of the act requires that a petitioner (for approval of a food additive regulation) describe the chemical identity and composition of the material proposed for food additive approval.

Affirmation of recycled animal waste as GRAS for specified uses, under provisions of sections 201(s) and 701(a) of the act, and 21 CFR 570.35 of the regulation, might also be considered, although the variability in composition of animal waste could make "generic" affirmation difficult. If, after notice and opportunity for comment, the Commissioner finds "convincing evidence" that the material is GRAS as defined in section 201(s) of the act, the substance will be affirmed as GRAS. A substance is GRAS if it is "* * * generally recognized, among experts qualified by scientists training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food before January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; * * *," (21 U.S.C. 321 (s)).

If GRAS affirmation of recycled waste were even considered, however, it almost certainly would be necessary to specify that one or more processing methods be utilized, or to establish criteria for processing. Any unavoidable poisonous or deleterious substances that might be present could be permitted as unavoidable contaminants, under section 406 of the act and 21 CFR Parts 109 and 509 of the regulations, via the promulgation of formal tolerances or action levels. See the FEDERAL REGISTER of September 30, 1977 (42 FR 52813). Such tolerances or action levels would necessarily be established at levels that have been determined not to be harmful to animals or man.

VIII. Conclusion

A. Current FDA Position

The foregoing discussion reveals that the agency has available to it a considerable amount of information with respect to the recycling of animal wastes. However, it is also apparent that additional information is needed to provide assurance that products from animals fed animal waste are safe for human consumption, especially if only minimal supervision by regulatory agencies is possible. Even if a regulatory program which would sanction use only under restriction of specific controls were to be proposed, information and comment would be needed with respect to the feasibility of such a program.

The Commissioner has determined that, pending review of data and comments received in response to this notice, the agency's regulatory posture with respect to recycled animal waste should remain unchanged. In other words, regulatory action will not be taken unless animal waste intended for use as animal feed were found to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, and unless violation of section 301 of the act had occurred.

B. Alternatives for the Future

The Commissioner has not determined what action, if any, will ultimately be taken with respect to modification of the agency's present regulatory position. He anticipates that at least six choices will be available to him, following evaluation of comments and data.

First, he could determine that no change in agency policy is indicated.

Second, he could determine that no change in agency policy is indicated for the time being, but request that additional research be conducted. Such data, when received, could be utilized as a basis for (1) proposing to sanction the feeding of animal waste, placing such limits on the practice as the data indicate would be desirable; or (2) proposing to ban the feeding of animal waste if the data fail to show that use of the material is safe, even under practicable control programs, and providing opportunity for the industry to submit evidence showing that the material is safe. This alternative would require several years while research is completed.

Third, he could propose a regulatory control program that prescribes certain characteristics for waste intended for feeding to livestock—e.g., maximum allowable levels of potentially harmful substances. Processing according to prescribed procedures could be required as an alternative to, or in addition to, the foregoing, as could withdrawal periods and possibly other forms of control. The probability that inherent controls—e.g., biological and economic limits on the amount of waste that can be fed, and other inherent controls as discussed in sections II and V—would be observed, and the likely extent of such controls, could be considered in developing such a proposal.

Fourth, the Commissioner could propose a regulatory control program as described in the preceding paragraph, but could also request that additional research be conducted as a basis for subsequent adjustments in the regulatory program.

Fifth, the Commissioner could propose to ban the feeding of waste, on the basis that currently available data fail to show that the material is safe even under practicable control programs, providing opportunity for the industry to submit evidence that the use of the material is safe.

Sixth, the Commissioner could propose to affirm processed animal waste as GRAS under certain conditions—e.g., where no drugs have been fed to the donor species, or propose to declare such waste to be a food additive which could be fed under provision of one or more food additive regulations.

Additional alternatives, or variations of the preceding alternatives, would also be possible. The present statement of policy could be expanded, setting forth criteria and standards in greater detail. A joint federal-state program could be proposed in connection with the alternative selected, as appropriate. As stated above, the Commissioner has not determined at this time whether to propose a change in current policy, but he believes that public discussion of the issues will facilitate his decision as to whether any change is appropriate in the future, and on what basis. For this reason, the Commissioner solicits (1) comments on the issues that have been identified in this document, including comments by experts on the GRAS/food additive status of recycled animal waste (see section VII.B.), and suggestions as to additional issues that should be considered; (2) comments on the suggested research needs as listed in section VIII.C., and elsewhere in this notice, and submission of data and information that are currently available and are relevant to the suggested research needs; and (3) comments and suggestions as to practicable regulatory controls that might be adopted.

The Commissioner states that while he is asking for the submission of data from research that has already been conducted, he is not, at this time, suggesting that specific research projects be undertaken, because the scope and extent of research needed may depend upon the degree of regulatory control that is considered for adoption. Such suggestions might be made, however, following evaluation of comments and data that are provided as a response to this notice. The Commissioner also advises that, if additional data are needed to support use of animal waste as animal feed, under provisions of the Federal Food Drug, and Cosmetic Act, the responsibility for obtaining the data will fall principally on the proponents of recycling of animal waste.

C. Additional Data and Information Needed

1. *General.* Because of the potential problems associated with the presence of microorganisms, drug residues, toxic elements and other naturally occurring substances, and environmental chemicals in animal wastes, more information is needed as to the identity and levels of many of these substances that actually appear in the waste before processing. Information is also needed as to the toxicological significane of such substances.

2. *Animal health.* As stated in section IV, few animal health problems have been reported where animals have been fed processed waste, and the problems that have been identified appear to be avoidable with minimal precautions. The Commission, however, recognizes that need may exist for additional information derived from studies designed specifically to assess the animal health effects of substances that could be present in animal waste. Therefore, he solicits (a) information from such studies that have already been conducted and are not cited in this notice, and (b) comments on the adequacy of the studies that have been conducted, and are cited in this notice, in demonstrating whether or not animal waste is safe as an animal feed ingredient.

3. *Human health.* As noted in section IV, the available data are inadequate, in many respects, to support approval of the use of waste as animal feed, at least without regulatory controls. The Commissioner considers it appropriate, therefore, to request submission of additional data that are currently available, and to invite comment on the identification of those areas in which research on animal waste appears to be indicated to answer questions related to human health. Additional research needs are indicated at several places in section IV. In addition, a detailed outline for proposed research related to drugs and drug metabolites has been developed, and is presented for comment below. The possibility that a withdrawal period might be considered, as an alternative to (or in addition to) the research proposal, was considered and is also discussed briefly below.

a. *Drugs and drug metabolites.*—i. *Proposed research.* As stated above, the Commissioner is not suggesting at this time that specific research projects be undertaken. Instead, he seeks comments and suggestions on research that could be undertaken to resolve unanswered questions. Accordingly, the following proposals is offered for comment:

The possible adverse effect on human health of feeding wasfe that contains drugs and drug metabolites to animals is one of the major concerns of scientists faced with making judgments about the safety of this practice. In general, reported studies designed to evaluate the safety of drug residues in recycled waste and reviewed by FDA did not address the problem of drug metabolites in the waste. This must be done in order to define the conditions of safe use of waste. The type of data required may be obtained through the use of drug molecules that have been labeled with a radioactive atom in a metabolically stable position. A consideration of the conditions of use,

the persistence of residues and the demonstrated safety of many of the currently regulated animal drugs will probably serve to remove the concern for safety of human food associated with recycling of waste from animals treated with these drugs. In certain cases however, the available information may provide an inadequate basis for a reasonable judgment concerning safety.

The following procedure is one example of a protocol that could be used to demonstrate the conditions of safe use of waste from animals treated with a drug which cannot be removed from concern by a consideration of other types of information. The details of the procedure will no doubt have to be modified to reflect questions related to specific intended uses of the waste. Such questions include whether the waste will be recycled to the same or to a different species, and whether waste from animals fed waste will be recycled again. The steps of the procedure are as follows:

(1) Radiolabeled parent drug should be administered at the maximum label recommended use level to animals whose waste is intended to be recycled, and the parent as well as its major metabolic products should be characterized and quantitated in the animal's waste.

(2) The levels and persistence of the parent compound as well as its major metabloic products should be determined in the edible tissues of animals fed waste that has been fortified with appropriate levels (determined in step one) of radiolabeled drug and its major metabolites.

The levels and persistence as determined in step (2) would then be interpreted in light of known safety data. The agency could then determine whether the feeding of waste from animals that had been fed the parent drug could be sanctioned and, if so, whether regulatory controls (e.g., species limitations, withdrawal periods, etc.) should be established.

Because drug metabolites often occur in the wastes of treated animals at levels higher than those observed in tissues, sponsors of recent new animal drug applications have, in many cases, conducted initial isolation and identification studies of metabolic products in waste. For this reason, some of the information sought in step (1) above may currently be available for recently approved or reevaluated marketed drugs. Data obtained in step (2) are completely lacking and must be obtained, at least for drugs of potential concern, e.g., those that are widely used, those known to be carcinogenic (but use is allowed because no residue occurs when administered by approved methods) or extremely toxic in other respects, and those drugs that are known to produce persistent residues in the edible tissues of treated animals.

ii. *Consideration of a withdrawal period for waste that contains drug residues.* The possibility of an alternative to the foregoing research project was considered by FDA during its deliberations of the past several years. Such an alternative might be a regulatory control program which specifies withdrawal periods as a means of eliminating or minimizing the possibility of residues of drugs or metabolites occurring. The following program was considered:

(1) Wastes containing drug residues could be fed to all species of livestock and poultry with the exception of dairy cattle producing milk for human food or laying hens producing eggs for human food, provided a withdrawal period (30 to 45 days) was observed before slaughter. Dairy cattle and hens could consume such wastes providing a withdrawal period of 30 to 45 days was observed before the production period.

(2) Wastes containing no drug residues could be fed to all species of livestock and poultry without a withdrawal period.

(3) Persons using or offering for sale animal wastes intended for use as animal feed would be required to obtain and maintain on a current basis a record of medication used in the herd or flock from which the waste was obtained.

However, FDA is aware that certain problems are inherent in such a program, where residues of drugs or drug metabolites occur in the waste. In the absence of a research effort designed to determine the level and the nature of the drug residues present in animal wastes and their persistence in the edible tissue of animals fed animal waste, FDA might not be confident that a 30- to 45-day withdrawal period would be adequate to reduce drug residues to levels deemed to be safe for human consumption. Also, if a withdrawal period is established, methods to monitor tissue residues should be in effect to detect any violations of that withdrawal period. Without research to determine the nature of the tissue residue found after the feeding of animal wastes, it would not be possible to establish the proper target organs and marker residues to be examined in the regulatory process.

Nevertheless, the Commissioner is aware that several States permit the feeding of drug-containing animal waste, with or without the requirement of a drug withdrawal period. In the interest of facilitating discussion of the means of resolving problems related to drug residues in animal waste, the Commissioner solicits reports of experience from the states, as well as other comments related to the feasibility of use of a withdrawal period or other regulatory control. The Commissioner welcomes suggestions of new approaches to enforcement of any prescribed withdrawal time for animal waste, such as mandating the addition of a dye or other readily analyzable substance to the waste.

b. *Other substances.* The discussions in section IV indicate that less extensive research may be necessary with respect to pesticides, and toxic elements and other naturally occurring contaminants of waste, than is outlined above for drugs. In general, the first task in these areas will be to validate methods of analysis already available for use in feeds and tissues for use in animal waste. Once the methodology has been shown to perform in an acceptable way in waste, levels of particular contaminants of concern can be determined in randomly selected samples of waste. If necessary, these methods could probably be adapted for use in regulatory control of these compounds in the recycled waste.

Additional research needs related to pathogenic organisms are discussed below.

4. *Processing methods (control of pathogenic organisms).*—a. *Proposed research.* As stated above, the Commissioner is not suggesting at this time that specific research projects be undertaken. Instead, he seeks comments and suggestions on research that could be undertaken to resolve unanswered questions. Accordingly, the following proposal is offered for comment:

A two-stage program of investigation is envisioned for development of data pertaining to the possible transmission of disease as a result of feeding animal waste to food-producing animals. The initial work should be directed to the question of whether feeding waste does in fact cause a significant increase in animal disease transmissible to man. If this is demonstrated, then research is needed to identify the parameters of waste processing sufficient to inactivate the particular pathogenic organism(s) responsible for the transmitted disease(s).

The following design for research on disease transmission should give useful results:

(1) Identify at least 20 animal waste feeding operations of commercial size with consideration of geographic distribution and range of practices;

(2) Identify the microbiology of the animal waste being fed;

(3) Select approximately 10 operations for further study based upon the microbiology of the animal waste, geographic distribution, range of practices, and availability of controls;

(4) For both treatment and control animals, record mortality, incidence and type of nonfatal disease, weight gain, feed conversion and visual observations of carcass and viscera upon slaughter. Through a statistically designed sampling plan, sample blood, spleen, lung, and intestinal contents and examine them for pathology and pathogenic microorganisms;

(5) Establish whether the increase in occurrence of organisms that are pathogenic to man (if any) and its attendant threat to man warrant the cost of processing animal waste according to specified procedures to eliminate pathogenic microorganisms.

Since the transmission of disease could build up with time, the study should cover at least 3 and preferably 5 years.

If the research shows that processing is needed, the Commissioner would need to know the minimum conditions required to inactivate the microorganisms of concern. At present, there are, as discussed elsewhere in this notice, several methods that appear to have potential for inactivating pathogens in animal

waste. Before any conclusions can be drawn about the merits of these methods, the following information is needed:

(1) Determine the pathogenic microorganisms likely to be in animal waste that are resistent to the process in question. This may be done through literature review and through experimentation;

(2) Establish suitable processing conditions for the resistant pathogens;

(3) Determine whether there is a naturally occurring microorganism, enzyme, or other compound that could be used as an indicator for determining whether the animal waste in question was properly processed;

(4) Conduct limited field trials to determine whether the laboratory-developed processing parameters are effective.

b. *Product standards alternative.* As an alternative to or in addition to the foregoing research program, standards for content of pathogenic organisms in recycled animal waste might be established, to be enforced by a regulatory control program. Such standards might require complete elimination of certain pathogens or, where safe levels can be ascertained, might provide for tolerances or action levels. The Commissioner solicits comments on the feasibility and parameters of such a program.

5. *Economics and environment.* The Commissioner has determined that he will consider the benefits of substances added to food as well as the risks inherent in such use, in determining whether the substances are "safe" for use. See the FEDERAL REGISTER of December 7, 1976 (41 FR 53600). Significant potential economic and environmental benefits are associated with the feeding of animal waste. To more fully assess the scope of such benefits, the Commissioner requests submission of the following kinds of information, if available:

(1) Volume of animal waste which can be recycled economically;

(2) Cost of feeding animal waste in processed form, and comparison with the cost of conventional sources of protein and other nutrients;

(3) Quantity of conventional feed ingredients that could be saved by feeding animal waste, and implications for crop acreage, cost of grains, and soybeans, etc.;

(4) The extent to which recycling animal wastes will reduce the amount of these wastes applied to crop and pasture lands (areas of the country where such impacts would most likely occur should be specified);

(5) The economic benefits and costs of feeding animal waste in comparison with other means of disposal of the waste, including effect of recycling on price of manure for use as fertilizer on crop and pasture lands;

(6) The potential for reduction of water and air pollution by feeding animal waste; and

(7) Any negative environmental implications of recycling animal waste.

6 *Information needed on use and enforcement experience; discussion of basis for State regulation.* It is unlikely that actual experience with the feeding of processed waste products can, by itself, provide the basis for affirming the substance as GRAS under provisions of the Federal Food, Drug, and Cosmetic Act, because common use before 1958 is required to support GRAS affirmation on the basis of use. Information available to the Commissioner indicates that common use of animal waste as a feed ingredient did not occur before 1958. Post-1958 products can be affirmed as GRAS only on the basis of scientific procedures, and scientific data are required to support approval of a food additive petition. Nevertheless, the Commissioner considers that information on the nature and extent of feeding of processed waste, and the problems encountered, if any, would be valuable in assessing the priorities to be placed on regulation of recycled animal waste, in evaluating the need for and the feasibility of regulating such products, and in determining the types of regulatory activity to propose, if any. Further, information gathered from experience under regulatory programs conducted by the States would be valuable in determining the nature and feasibility of federal regulatory activities, and in deciding whether to propose joint federal-state programs. Therefore, the Commissioner solicits data and coments related to the commercial use and regulation, in the various States, of recycled animal waste.

D. CRITERIA FOR PROCESSED ANIMAL WASTE; OPPORTUNITY FOR COMMENT

During its deliberations of the past several years, the FDA gave serious consideration to the development of a regulation that would establish conditions under which processed animal waste could be fed to livestock and poultry. The regulation would have established, among other things, minimum requirements for nutrient content; maximum allowances for moisture, microorganisms, toxic elements, drug residues, and pesticides; and labeling requirements. Although a draft regulation and preamble were developed in some detail, FDA ultimately decided not to propose the regulation.

As stated previously, the Commissioner has not eliminated from his consideration any possible alternatives for the regulation of the feeding of processed animal waste. Therefore, in view of his goal of maximizing participation and comment from the public, the Commissioner is placing on file with the Hearing Clerk a copy of the draft regulation and preamble, dated January 15, 1975. The public is invited to comment on these materials.

The Commissioner advises that ordinarily early drafts of FEDERAL REGISTER documents are not made available for public review and comment since such drafts are not part of the administrative record that must be made available for public comments. He has concluded, however, that under the unique circumstances involved in this situation, an exception should be made and the earlier draft should be made available for comment. These circumstances include (1) the fact that FDA has not reached a conclusion as to whether it wishes to make a change in its current policy, and therefore FDA is not offering a proposal in this notice; (2) the fact that the earlier draft could represent an approach that might ultimately be proposed by the Commissioner; (3) the Commissioner's desire to maximize public comment and participation; and (4) the fact that the document is not merely an early draft of this notice, but represents an entirely different approach.

E. ENVIRONMENTAL AND ECONOMIC IMPACT

The Commissioner concludes that, since agency action is not being proposed in this notice, there is no need at present for preparation of a formal economic impact assessment, or an economic impact statement. Nor is there need for a formal environmental impact analysis report or an environmental impact statement at this time. As discussed above, however, the recycling of animal waste has important economic and environmental implications and, if the Commissioner later determines that formal action is to be proposed, the necessary assessments will be made as an integral part of the determination of such proposed action.

F. OPPORTUNITY FOR COMMENT

Interested persons may, on or before June 26, 1978, submit written comments and data to the Hearing Clerk, Food and Drug Administration.

The Commissioner advises that, in order to maximize public comment on this document, copies of this notice are being mailed to the directors of the agricultural experiment stations and the cooperative extension services in each State, and to the professional societies in the animal sciences. Copies of the mailing lists have been placed on file with the Hearing Clerk. Notice of this publication is also being given to consumers through the FDA Consumer Update.

The Commissioner also advises that, after analysis of comments and data which are submitted, an oral public hearing before the agency may be scheduled under provision of the appropriate FDA regulations. Other possible sources of additional advice to the agency that might be utilized include conferences and advisory committees involving State feed control officials, research scientists and extension educators, representatives of the livestock industry, and consumer groups.

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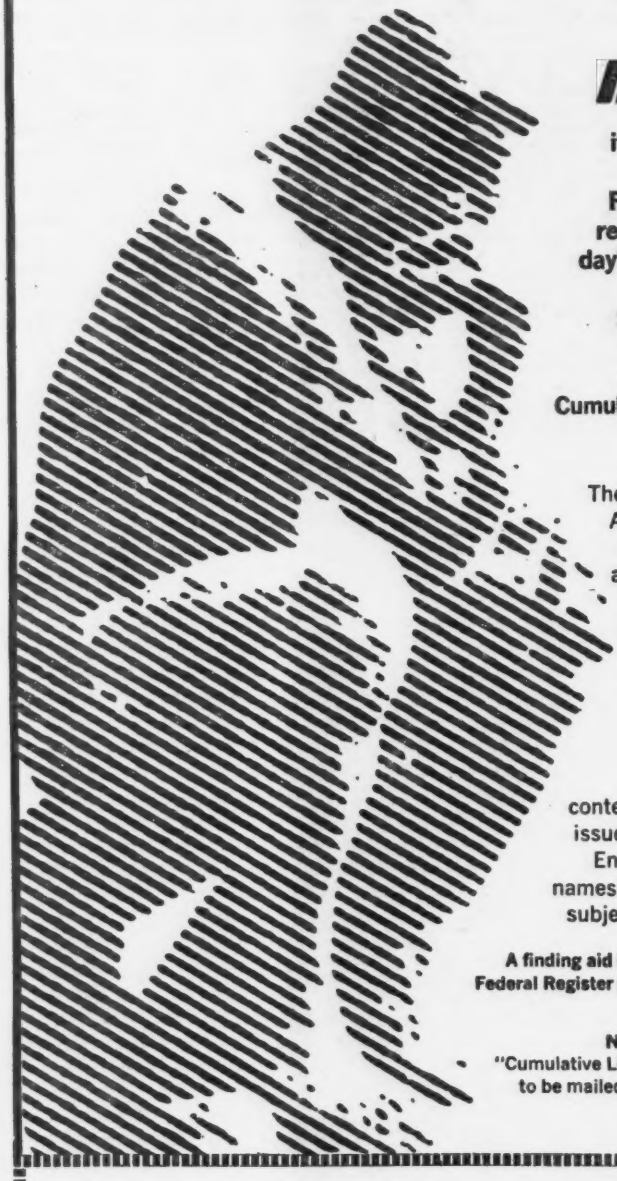
Interested persons may, on or before June 26, 1978 submit written comments and data to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md 20857. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Also available for public inspection are copies of relevant documents including literature cited in this notice.

Dated: December 15, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77–36739 Filed 12–23–77;8:45 am]



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